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Sand Diego, CA 92122

In re Application of :  
LI, Chuan :  
Serial No.: 10/068,664 :Decision on Petition  
Filed : February 6, 2002 :

This letter is in response to the letter filed on June 19, 2007 requesting reconsideration of the restriction requirement. It is presumed that the Petition from requirement for restriction was made under 37 C.F.R. 1.144 and has been treated as such.

**BACKGROUND**

On November 4, 2003, the examiner mailed a restriction requirement in which the original claims 1-15 were divided into 5 groups.

On December 1, 2003, Applicants filed a listing of claims.

On December 19, 2003, a non-responsive amendment was mailed to applicant requesting election of a specific group.

On January 12, 2004, Applicants elected Group I (Claims 1-5) without traverse.

On March 22, 2004, the examiner mailed to applicant a non-final Office action, in which Group I (Claims 1-5) were searched and examined on the merits. The claims were rejected on 102(b), 112/1<sup>st</sup> Written Description and 112/2<sup>nd</sup>.

On June 21, 2004, applicants filed a response to the outstanding office action.

On October 19, 2004, the examiner considered applicant's response and mailed a FINAL rejection.

On January 18, 2005, Applicants requested continued examination and added new claims 16-20.

On February 1, 2005, the examiner mailed to applicant a non-compliant amendment for failing to list the withdrawn claims' text.

On February 10, 2005, Applicant filed a response to the non-compliant amendment letter listing the withdrawn claims.

On March 9, 2005, the examiner mailed to applicant a non-final Office action, in which Group I (Claims 16-20) were searched and examined on the merits.

On June 7, 2005, Applicants filed a response to the outstanding rejection.

On August 25, 2005, the examiner mailed to applicant a non-compliant amendment for failing to have proper status identifiers.

On September 14, 2005, Applicant filed a response to the non-compliant amendment letter listing the withdrawn claims.

On November 28, 2005, the examiner considered applicant's response and mailed a FINAL rejection.

On February 24, 2006, Applicants requested continued examination and added new claims 21-25 containing multiple DNA sequences defined by SEQ ID NO: 32-41.

On May 16, 2006, the examiner mailed a restriction requirement in which Claims 21-25 were divided into 10 groups corresponding to each of the identified SEQ ID Nos.

On June 15, 2006, Applicant responded to the restriction requirement by canceling Claims 21-25 and adding new claims 26-40 directed in part to SEQ ID NO: 37, 39, 41.

On September 19, 2006, the examiner mailed a non-responsive letter to applicant requesting election of a specific group. The examiner noted that following the amendments to the claims, groups VI, VIII and X were remaining.

On October 10, 2006, the Applicant elected group VI and VIII.

On December 28, 2006, the examiner mailed a letter indicating the election was non-responsive because Applicant elected both Group VI and VIII for prosecution.

On January 22, 2007, Applicants filed a provisional election of Group VI to be examined (Claims 26-30) with traverse and arguments.

On April 20, 2007, the examiner mailed an Ex Parte Quayle Action requesting applicant cancel the non-elected inventions.

On June 19, 2007, the Applicant filed a response and applicants filed this petition to request that the Office reconsider the restriction requirement.

## DISCUSSION

The petition and extensive file history have been carefully considered.

An OG Notice published March 27, 2007 indicated that the standard of independence and distinctness would be applied to polynucleotide claims filed in an application under 35 USC 111(a).

Additionally, the March 27, 2007 OG Notice specifically spoke to the issue of burden of searching more than one independent and distinct invention.

The petition asserts that SEQ ID NO: 37, 39, 41 must be examined together because the plasmids are related. The plasmid are allegedly synthesized by the same design, are initially designed for the same purpose, made by the same method and can be sued together and are used together in a single product.

### Consideration of Independent and Distinct Inventions

35 U.S.C. 121 sets forth the appropriate means for restriction which permits,

“If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions.”

MPEP 802.01 helps define the terms independent and distinct.

The term “independent” (i.e., unrelated) means that there is no disclosed relationship between the two or more inventions claimed, that is, they are unconnected in design, operation, and effect. Related inventions are distinct if the inventions as claimed are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER (though they may each be unpatentable over the prior art).

The MPEP also provides guidance in 806.01, stating

“In passing upon questions of double patenting and restriction, it is the claimed subject matter that is considered and such claimed subject matter must be compared in order to determine the question of distinctness or independence.”

Finally, “Where the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction there between should never be required. This is because the claims are not directed to distinct inventions; rather they are different definitions of the same disclosed subject matter, varying in breadth or scope of definition” (see MPEP 806.06).

An alignment between SEQ ID NO: 37, 39, and 41 reveals only minimal homology over the full plasmid DNA. The sequences share approximately the first 750 nucleotides in common. However, the remaining nucleic acid sequence share no homology. Thus, a sequence of SEQ ID NO: 37 does not appear obvious over either SEQ ID NO: 39 or 41. This argument has been reviewed but is not persuasive. The sequences thus appear to be both independent and distinct.

The petition further asserts that the recently issued patents claimed multiple plasmids. This argument has been thoroughly reviewed but deemed not persuasive because each application for a patent is reviewed on its own merits for independence and distinctness. Moreover, restriction is discretionary especially in the cases where an examiner deems no burden exists. Here, the examiner has set forth both distinctness, independence and burden by indicating a separate search.

Finally the petition asserts that the plasmids claimed are small plasmids which are only 1906, 2315 and 1982 base pairs. The petition asserts that the burden of search is proportional to the plasmid size stating that the larger the plasmid, the more sequence would need to be searched. This argument has been reviewed but is not persuasive. A search for a longer sequence would more likely result in review of a fewer number of sequences. A shorter sequence fragment, such as 10-mers, would be expected to identify a larger number of sequences needing to be considered for novelty and obviousness. Thus, the size of the plasmids does not provide indicia of burden of search or independence and distinctness.

The MPEP sets forth a means for applicant to assert on the record that SEQ ID NO: 37, 39, 41 are obvious variants over one another and as such are not independent or distinct. Specifically, the MPEP provides that "Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention." The applicants do not appear to have availed themselves of this opportunity to place such evidence or statements on the record.

Thus, for the reasons provided above, the requirement to the elected invention, SEQ ID NO: 37 has been affirmed.

## DECISION

The petition is **DENIED** for the reasons set forth above.

Any request for reconsideration must be filed within two (2) months of the mailing date of this decision.

Should there be any questions about this decision, please contact Special Program Examiner Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above,

or by telephone at 571-272-1600 or by facsimile sent to the general Office facsimile number, 571-273-8300.

A handwritten signature in black ink, appearing to read "Christopher Low". The signature is written in a cursive, flowing style.

Christopher Low  
(Acting) Director, Technology Center 1600  
jb/jg